



Caladrius Biosciences Announces Presentation of Full Results for CLBS16 from the ESCaPE-CMD Trial at SCAI 2020 Scientific Sessions

May 6, 2020

BASKING RIDGE, N.J. (May 6, 2020) – Caladrius Biosciences, Inc. (Nasdaq: CLBS) ("Caladrius" or the "Company"), a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, disease, today announced it will present full data results from the ESCaPE-CMD trial of Caladrius's autologous CD34+ cell therapy, CLBS16, at the Society for Cardiovascular Angiography and Interventions ("SCAI") 2020 Scientific Sessions Virtual Conference being held virtually May 13-16, 2020.

Oral presentation details:

Session Type:	Featured Clinical Research
Title:	<i>Autologous CD34 Cell Therapy for Treatment of Coronary Microvascular Dysfunction in Patients with Angina and Non-Obstructive Coronary Arteries</i>
Date & Time:	Thursday, May 14, 2020 at 3:40p.m. (ET)
Link to Session:	https://scai.confex.com/scai/2020/meetingapp.cgi/Paper/11492

The ESCaPE-CMD^[1] trial was an interventional, proof-of-concept study designed to evaluate the ability of Caladrius's autologous CD34+ cell therapy (CLBS16) to reverse the underlying pathology of CMD, the loss of microcirculation, and thereby alleviate symptoms. The key endpoint was measurement of the change from baseline of coronary flow reserve, a direct measure of microvascular function, at six months following a single injection of CLBS16. The trial completed enrollment of the targeted 20 patients in May of 2019 and the last patient completed the 6-month follow up in December of 2019. Dr. Timothy Henry will present the findings. The study's three principal investigators are Dr. C. Noel Bairey Merz, Cedars-Sinai Medical Center, Los Angeles, CA, Dr. Timothy D. Henry, The Christ Hospital, Cincinnati, OH and Dr. Amir Lerman, The Mayo Clinic, Rochester, MN. All patients received a single infusion of their own GCSF-mobilized CD34+ cells formulated as CLBS16.

About Coronary Microvascular Dysfunction

Coronary microvascular dysfunction is a type of non-obstructive coronary artery disease that causes decreased blood flow to the heart muscle that affects approximately 8.3 million^{2,3} people in the U.S. With common symptoms that include recurring, debilitating chest pain, tiredness, and shortness of breath, many CMD patients are undiagnosed because of the absence of large vessel obstruction. Due to a misunderstanding of the disease, patients, the majority of whom are women, often go years without proper treatment. When a diagnosis of CMD is missed, patients are untreated and remain at high risk of heart attack and/or cardiovascular-related death.

About Caladrius Biosciences

Caladrius Biosciences, Inc. is a clinical-stage biopharmaceutical company dedicated to the development of cellular therapies designed to reverse, not manage, cardiovascular disease. We are developing a first-in-class cell therapy product that is based on the notion that our body contains finely tuned mechanisms for self-repair. Our technology leverages and enables these mechanisms in the form of specific cells, using formulations and modes of delivery unique to each medical indication.

The Company's current product candidates include three developmental treatments for ischemic diseases based on its CD34+ cell therapy platform: CLBS12, recipient of SAKIGAKE designation and eligible for early conditional approval in Japan for the treatment of critical limb ischemia ("CLI") based on the results of an ongoing clinical trial; CLBS16, the subject of a recently completed positive Phase 2 clinical trial in the U.S. for the treatment of coronary microvascular dysfunction ("CMD"); CLBS14, a Regenerative Medicine Advanced Therapy ("RMAT") designated therapy for which the Company has finalized with the U.S. Food and Drug Administration (the "FDA") a protocol for a Phase 3 confirmatory trial in subjects with no-option refractory disabling angina ("NORDA"); and CLBS119, a CD34+ cell therapy product candidate for the repair of lung damage found in patients with severe COVID-19 infection who experienced respiratory failure, for which the Company plans to initiate a clinical trial in the coming months. For more information on the company, please visit www.caladrius.com.

Contact:

Investors:

Caladrius Biosciences, Inc.
John Menditto
Vice President, Investor Relations and Corporate Communications
Phone: +1-908-842-0084
Email: jmenditto@caladrius.com

Media:

W2O Group
Christiana Pascale
Phone: +1-212-257-6722
Email: cpascale@w2ogroup.com

^[1] Funding for the Phase 2 ESCaPE-CMD study came, in part, from a \$1.9 million grant from the National Institutes of Health under award number R44 HL135889. The content of this press release is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

²Mittal, S.R.; Indian Heart Journal, Volume 66, 2014, Pages 678–681

³Cleveland Clinic/AHA (American Heart Association)



Source: Caladrius Biosciences, Inc.